K 101716

510(k) SUMMARY
HVR Lamp

JAN 1 1 2011

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. Submitter's Information

Name:	HVR, LLC
Address:	7821 Orion Avenue, Suite 200 Van Nuys, CA 91406 Phone: (818) 217-2556 Fax: (818) 217-3556
Contact:	Jessany Garrett Director of Legal Affairs
Date Prepared:	November 6, 2010

2. Device Information

Trade/Proprietary Name:	HVR Pain Relief Device
Common/Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp, Therapeutic Heating (21 CFR 890.5500)
Product Code:	ILY

3. Predicate Device

- Quantum WARP 10 (K032229, November 3, 2003)

4. Intended Use

The HVR Lamp is an over-the-counter handheld device used for the treatment of chronic pain by emitting energy in the near-infrared spectrum for the temporary relief of minor aches and pains in muscles and joints, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

5. Device Description

The HVR Lamp is a pain relief device consisting of a hand-held module containing an array of 48 near-infrared (red) LED's, user controls and a power supply. The unit is intended to emit energy in the near-infrared spectrum for the temporary relief of pain in the muscles and joints. The HVR device operates on a continuous frequency providing

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ninety (90) seconds of treatment time per application. The user powers on the unit by pressing the power button. Once powered on, the LEDs illuminate and the user places the device over the desired treatment area. The unit automatically shuts off at the end of the treatment time. Details are provided in the Device Description Section of this submission.

6. Substantial Equivalence

The HVR Lamp is substantially equivalent to its predicate device when intended for use for the treatment of chronic pain by emitting energy in the near-infrared spectrum for the temporary relief of minor aches and pains in muscles and joints, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied. The data in this 510(k) notification demonstrates that the HVR device shares the same intended use, design features and functional features and is therefore substantially equivalent to its predicate devices. There are very minor differences between the HVR Lamp and the predicate device including a more ergonomic design and larger overall unit size; however the treatment area, number and type of LEDs, light intensity and wavelength, frequency setting options and electrical safety features are the same in both devices. The minor differences between the HVR Lamp and the predicate device do not raise any new issues of safety or efficacy. A comparison of the HVR Lamp and the Quantum WARP 10 device is presented in the table below:

HVR	Quantum WARP 10
Basic Device Design: Handheld module with circular treatment area	Basic Device Design: Handheld module with circular treatment area
Target Skin Temperature: Minimum 39° C and maximum 45° C	Target Skin Temperature: Minimum 39° C and maximum 45° C
Radiation: Low powered LED diodes are extremely safe as Class II device	Radiation: Low powered LED diodes are extremely safe as Class II device
Indications for use: The HVR Lamp is an over-the-counter handheld device used for the treatment of chronic pain by emitting energy in the near-infrared spectrum for the temporary relief of minor aches and pains in muscles and joints, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied.	Indications for use: The Quantum WARP 10 Light Delivery System is a handheld device used for the treatment of chronic pain by emitting energy in the near-infrared spectrum for the temporary relief of minor muscles and joint pain, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied.
Light Intensity: 50 – 80 mW/cm^2	Light Intensity: 50 – 80 mW/cm^2

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Wavelength: Near Infrared 650nm to 950nm Waveform: Constant Energy Delivery: Handheld treatment probe; Multi diode dispersed over treatment area Dimension: 69.85 mm x 164.3 mm x 77.72 mm Materials: Rigid ABS Effective treatment area: 1000 mm^2 (10 cm^2) Diodes: 48 near-infrared (red) Frequency: One continuous setting Additional safety option: 90 second automatic shut off Electrical safety options: AA disposable batteries and A/C wall plug adaptor, or AA rechargeable batteries	Wavelength: Near Infrared 650nm to 950nm Waveform: Constant Energy Delivery: Handheld treatment probe; Multi diode dispersed over treatment area Dimensions: 67 mm x 141 mm x 51 mm Materials: Rigid ABS Effective treatment area: 1000 mm^2 (10 cm^2) Diodes: 48 near-infrared (red) Frequency: One continuous setting Additional safety option: 90 second automatic shut off Electrical safety options: AA disposable batteries and A/C wall plug adaptor, or AA rechargeable batteries

7. Testing Summary

Testing for the HVR Lamp has been carried out to verify that the device meets all functional and technical specifications per IEC 60601-1-1-2005 and to ensure that the temperature at the skin surface where the device is applied is acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HVR, LLC
% Mr. Jessany Garrett
Director of Legal Affairs
7821 Orion Avenue, Suite 200
Van Nuys, California 91406

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Re: K101716
Trade/Device Name: HVR Infrared Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: November 05, 2010
Received: November 08, 2010

Dear Mr. Garrett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

JAN 1 1 2011

510(k) Number (if known): K101716

Device Name: HVR Infrared Lamp

Indications for Use:

The HVR device is an over-the-counter handheld device used for the treatment of chronic pain by emitting energy in the near-infrared spectrum for the temporary relief of minor aches and pains in muscles and joints, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

Prescription Use_____ AND/OR Over-the-Counter Use__X__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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(Division Sign-Off)
Division of General Restorative Devices

510(k) Number_____